UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY PRODUCTS LIABILITY LITIGATION	)	**MDL No. 1:13-md-2419-FDS**
This Document Relates to:	)	**Judge Rya W. Zobel**
All Cases	)	

MOTION OF DEFENDANT AMERIDOSE LLC TO PROCEED WITH FDA-AUTHORIZED DESTRUCTION OF RECALLED INVENTORY

I. INTRODUCTION

Ameridose asks this Court for an Order authorizing the destruction of the recalled inventory it is currently holding. Although the company has not been operating since the fall of 2012, Ameridose is currently holding a large volume of products which were returned to Ameridose in response to its voluntary recall of all products from the market. The recall was completed months ago, and both federal and state regulators agree that Ameridose should now dispose of these expired products in a safe manner. In fact, the Food and Drug Administration ("FDA") and the Drug Enforcement Administration ("DEA") have both approved a plan for Ameridose to turn all of the recalled products to a third-party reverse distributor who will destroy the products under FDA's observation.

Destruction of the products is appropriate for numerous reasons. First, these products are expired and destruction will ensure that the products are permanently removed from circulation. Second, the DEA has asked that Ameridose surrender its DEA controlled substances licenses. Without a valid DEA license, if Ameridose is not permitted to destroy the recalled controlled substance products, the DEA likely will have to take possession of this inventory, and take over

the responsibility of sealing and routinely inspecting the product at the Ameridose facility. This is an unnecessary administrative expense and complication for all concerned, which can and should be avoided[1]. Third, continued secure storage of these products is costly, and as Ameridose is not operating, this expense is becoming difficult to meet. Lastly, there also is no reason to continue to preserve the recalled products. No litigation has been filed against Ameridose over any of the recalled products. The pending litigation centers on Plaintiffs' claims that they developed fungal meningitis or meningitis-related injuries after receiving injections of allegedly contaminated Methylprednisolone Acetate ("MPA") designed, compounded, and distributed by New England Compounding Pharmacy, Inc. (a/k/a NECC), not Ameridose.

The recall is over. MPA is not a part of Ameridose's recalled inventory, and there are no Ameridose-product lawsuits. Both FDA and DEA not only support Ameridose's desire to destroy the remainder of its inventory, but have approved the plan to implement it. Therefore, Ameridose hereby moves the Court for an order allowing it to destroy all recalled inventory.

II. RELEVANT FACTS.

The product at issue in this MDL is MPA, which was compounded and distributed by NECC.[2] Almost every complaint, and every PSC subpoena, motion, and every submission to the Court emphasizes that fact, including the PSC's recent status report (Docket #1005). So does the medical literature.[3] It is undisputed that Ameridose LLC did not compound, manufacture or

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[1] Ameridose's licensing counsel has continuing communications with the DEA; the DEA is aware that Ameridose is awaiting the Court's decision on this motion.

[2] There are only two or three cases alleging a defect in a different NECC product.

[3] *See, e.g.,* Rachel Smith, et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, NEJM, 369; 17, pp. 1598-1609 (2013), attached as Exhibit F.

distribute Methylprednisolone Acetate, the drug allegedly responsible for the 2012 fungal meningitis outbreak.

In October 2012, Ameridose ceased operations and on October 31 voluntarily recalled all (2,200) of its products. (*See* Affidavit of Ingrid Martin, Ex. A, ¶ 3, and http://www.fda.gov/Safety/Recalls/ucm326349.htm (Press Release Announcing Recall.).) The recall notice and overall recall plan was approved by FDA. (*See* 21 C.F.R. §7.42; Martin Aff., Ex. A, ¶ 4 and Ex. B.) Ameridose's recall notice did not list MPA as a product that it compounded, manufactured, or distributed. (*See* Recall Notice, Ex. 1; Docket #111.). Nor did FDA's website. (*See* FDA reports voluntary recall of all Ameridose drug products, http://www.fda.gov/drugs/drugsafety/fungalmeningitis/ucm326384.htm (listing of all products recalled by Ameridose). Even though AMD has never believed the recalled products were relevant or meet the FRCP 26 discovery standard, out of an abundance of caution it preserved all of this material as it came back from customers.

By June 21, 2013, the recall was almost complete. (Martin Aff., ¶5; Ex. C.) As a result, Ameridose looked forward to the ultimate end of the process – destruction of the recalled products. It approached DEA & FDA with a proposal. That request explained:

> Ameridose is seeking to return and dispose these products for a number of reasons. First, Ameridose will suffer substantial financial harm if it misses the opportunity to return expired bulk products within the time frame set by the vendor. Second, the large quantity of narcotics that are now at Ameridose pose risks that Ameridose would like to eliminate. Although Ameridose has a good security system in place, the sheer quantity of narcotics that have been accumulated through the recall process is a concern. It would be best to eliminate any possibility of theft by returning or destroying these controlled substances. Third, to ensure the continued security of Class II substances, Ameridose is conducting a weekly inventory count. Given the amount of product on hand, this is a costly endeavor. Finally, Ameridose would like to clear out space and have the ability to make whatever changes regulators will recommend for reopening the facility.

(Ex. C.) First, the DEA agreed. (Martin Aff., Ex. A, ¶ 6; Ex. D.) Then FDA agreed (Martin Aff. ¶7; Ex. E). Between mid-July and mid-October, 2013, Ameridose and FDA/DEA worked out the details and reached final agreement on the destruction strategy. (Martin Aff., ¶8, 9, 10 & 11, Exs. F, G, H, and I.)

To date, not a single case in the MDL alleges that a specifically identified Ameridose product was contaminated and caused harm. (Martin Aff., ¶19.) AMD is not storing any recalled MPA for NECC. (Martin Aff. ¶18)

Ameridose's recalled inventory consists of over half a million "units." (Martin aff., Ex. A, at ¶ 13, Ex. F). It occupies over 3,000 square feet of AMD warehouse space in Westborough, Massachusetts, including over 1,000 square feet of space in the company's security vaults. (*Id.* at ¶ 13). The recalled inventory consists of intravenous or injectable medications with short shelf life, which are well beyond its expiration dates of January, 2013. They cannot legally be sold or prescribed. (*Id.* at ¶ 15.) In addition, much of the recalled inventory consists of "scheduled" drugs (*i.e.*, narcotics), the storage of which requires high security facilities and protocols, and additional regulation required administrative tasks. (*Id.* at ¶¶ 13-14.)

Lastly, the DEA has recently contacted counsel for Ameridose and asked that the company voluntarily surrender its DEA Controlled-Substances licenses. The DEA also informed counsel for Ameridose that federal regulation requires a DEA Controlled-Substances license for any entity that maintains possession of any controlled substances. In order to effectuate the voluntary surrender of the licenses the DEA has requested that Ameridose dispose of all controlled substances in its possession, and has, as mentioned above, approved of a procedure to remove and destroy the products. (*Id.* at ¶¶ 16-17.)

III. LAW AND ARGUMENT

A. This Court Has the Authority to Permit the Destruction

The Court should exercise its authority to allow Ameridose to properly and safely dispose of the recalled products. Courts are invested with broad inherent powers to manage all phases of a litigation so as to achieve the orderly and expeditious disposition of cases. *See McGuire v. Acufex Microsurgical, Inc.*, 175 F.R.D. 149, 153 (D. Mass. 1997) (*quoting Chambers v. NASCO, Inc.*, 501 U.S. 32, 43 (1991)); *Citizens for Consume v. Abbott Labs.*, No. 01-12257-PBS, 2007 WL 7293758 (D. Mass. Mar. 26, 2007). Specifically, courts have the authority to order that evidence be preserved and may impose sanctions on a party for its failure to preserve evidence. *Id., see also Pueblo of Laguna v. United States*, 60 Fed. Cl. 133, 135 (2004).[4]

Similarly, courts have ordered that potential evidence be destroyed if the circumstances indicate that the evidence need not be preserved. *See, e.g., In re: Pet Food Prods. Liab. Litig.*, 345 Fed. App'x. 857, 859 (3d Cir. 2009) (ordering destruction of recalled inventory by granting protective order allowing defendants to destroy all but a sampling of recalled inventory); *Brandner v. Abbott Labs., Inc.*, No. 10-3242, 2011 WL 2457683, *4 (E.D. La. June 16, 2011) (same); *In re: Digitek Prod. Liab. Litig.*, MDL No. 1968 (S.D. W. Va. Mar. 10, 2010) (ordering destruction of non-Digitek recalled product) (unpublished Pretrial Order #55, attached as Exhibit J. In determining whether to exercise the authority to order the destruction of recalled inventory, courts consider the cost and undue burdens posed with maintaining large quantities of recalled inventory, the potential for accidental misuse or theft, and whether FDA (or any other

[4] Other jurisdictions are in accord with the proposition that courts have the inherent power to manage the preservation of evidence. *See U.S. v. Salad*, 779 F. Supp. 2d 503, 507-08 (E.D. Va. 2011); *United States v. Boeing Co.*, No. Civ. A. 05-1073-WEB, 2005 WL 2105972, *2 (D. Kan. Aug. 31, 2005); *Capricorn Power Co., Inc. v. Siemens Westinghouse Power Corp.*, 220 F.R.D. 429, 431 (W.D. Pa. 2004).

regulatory agency) has recommended the recalled products be destroyed. *See Brandner*, 2011 WL 2457683 at *3-4.

Here, the cost-benefit analysis, as well as circumstances involved, indicate the evidence need not be preserved. As an initial matter, the preservation and storage of the recalled inventory imposes substantial operational and financial burdens on Ameridose. Ameridose cannot use the substantial space currently housing the recalled inventory for other storage purposes, or potentially leasing the space to others. Moreover, housing the recalled inventory requires Ameridose to employ personnel to watch the products. (*Id.* at ¶¶ 13-14). Much of the recalled inventory consists of "scheduled" drugs (*i.e.,* narcotics), the storage of which requires high security facilities and protocols. (*Id.* at ¶¶ 13-14.) Despite the security, there is always the risk of theft, here potentially on a massive scale. These recalled products have substantial black market value, and Ameridose, as well as government regulators, wish to ensure that there can be no opportunity for diversion. In addition, the medication is expired and cannot legally be sold or prescribed. (*Id.* at ¶15.) Accordingly, these expenses and risks impose a significant burden, financial and otherwise, on Ameridose.

There is no benefit to forcing Ameridose to continue to incur the cost of preservation. Critically, Ameridose has not been sued over any of *its own products.* Keeping non-MPA products is irrelevant to the litigation. And there have been no test results confirmed by FDA or any other regulatory agency demonstrating that a contaminated Ameridose product was placed into the marketplace. Requiring Ameridose to continue to store this recalled inventory will only further perpetrate the unnecessary operational and financial burdens frowned upon by the *Brandner* court.[5]

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[5] Note, these burdens will not be remunerated if the DEA is forced to take possession of the drugs. It is likely that the drugs will remain in place at Ameridose and the DEA will simply place a seal on the area containing the

Plaintiff has not even inquired about examining or testing the recalled inventory during the near-sixteen months in which this litigation has been pending. This is not surprising because none of Ameridose's recalled inventory contains MPA and, therefore, nothing in the inventory could have caused a plaintiff any harm with respect to claims arising from this litigation. Plaintiffs have had more than enough time to examine this potential evidence. Ameridose's duty to preserve evidence – assuming one even existed – does not continue indefinitely.[6] Ameridose cannot be expected to continue to carry the burden of preserving this inventory when Plaintiffs have shown no interest in it since this litigation began. *See Zolo Techs. v. Roadway Express*, No. CIVA05CV00494EWNMEH, 2006 WL 898132, *3 (D. Colo. Apr. 4, 2006).

B. Both FDA and DEA Have Recommended the Destruction of Ameridose's Recalled Product and Their Expertise Deserves Deference.

Pursuant to 21 C.F.R. § 7.42, Ameridose's recall strategy – from start to finish – has been governed by agreements between FDA and Ameridose. This is because Congress empowered FDA with the authority to oversee recalls under the Food, Drug & Cosmetic Act ("FDCA"). *See,* 21 C.F.R. §§ 7.40-.42 (discussing FDA's authority to enter into and oversee all aspects of a company's recall strategy); *see also In Re Human Tissue Prods. Liab. Litig.,* 488 F. Supp. 2d 430, 433 (D.N.J., 2007) ("The regulations implementing the Federal Food, Drug and Cosmetic Act vest the FDA with the authority to monitor and supervise product recall."); *United States v. C.E.B. Prod., Inc.*, 380 F. Supp. 664, 668 (N.D. Ill. 1974) ("recalls have played an increasingly significant role in the FDA's enforcement of the [FDCA].").

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product. This approach would require Ameridose to continue to maintain the procedures it currently have in place with the additional burden on the company and the government of requiring periodic inspection by the DEA to ensure that the seal remains in place.

[6] Plaintiffs arranged for an inspection of NECC promptly after the litigation was filed. There has never been such a request to AMD.

Courts traditionally defer to the primary jurisdiction of FDA in matters where its specialized expertise justifies deferral to its judgment in enforcing its regulatory authority. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) (noting that courts defer to FDA's regulatory process because "the heart of new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created."); *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 767-68 (1947) (finding the primary jurisdiction doctrine applicable where Congress has delegated initial or exclusive responsibilities to an administrative agency to resolve certain issues in complex matters in which the agency has special competence). This is especially true in the context of recalls, which have traditionally fallen within FDA's primary jurisdiction. *See Clark v. Actavis Group hf*, 567 F. Supp. 2d 711 (D.N.J. 2008) (declining to interfere with prescription drug recall based on FDA's primary jurisdiction); *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d at 432-33 (finding that the content of recall notice was best left to FDA, where FDA had guidelines for the format, content, and extent of recall communications and exercised oversight of recalls). Under the doctrine of "'primary jurisdiction,' when an activity is arguably subject to an administrative agency's expertise, such as FDA, federal courts must defer to the exclusive competence of that agency." *In re Human Tissue Prods. Liab. Litig.*, 488 F.Supp.2d at 433 (citing cases).

Here too, FDA has expertise in the mechanics of Ameridose's product recall and agrees, along with DEA, that Ameridose's recall products should be destroyed. The recall process here, while voluntary, was still done pursuant to FDA oversight. Specifically, Ameridose requested FDA's permission to recall, as well as a specific process for that recall designed to keep these products out of the wrong hands, protect the public from expired drugs, and assure the product was destroyed in an environmentally safe manner. FDA approved that request. (Exhibit B)

Next, as the recall neared completion, Ameridose turned to the topic of destruction of the product and proposed a process (Exhibit C), to which the DEA agreed, and then FDA, agreed. (Exhibits D and E) Through further correspondence, Ameridose, FDA and DEA clarified the details and reached agreement to a final, approved process. (Exhibits F, G, H and I) This is the very type of agency action which deserves deference: scientific and logistic oversight by professionals with expertise in the business, the process and the considerations for safety and security. Accordingly, this Court should defer to FDA (and DEA) and order that Ameridose be permitted to destroy its recalled products.

IV. CONCLUSION

Ameridose has diligently maintained all of its recalled inventory in an abundance of caution to comply with any arguable preservation obligations in this litigation, even though it never designed, compounded, manufactured, or distributed MPA, the drug that is allegedly responsible for the meningitis outbreak. Preserving this inventory has, and will continue to, impose material operational and financial burdens on Ameridose. It is FDA and DEA's position that this inventory should be destroyed. Accordingly, Ameridose should be relieved of its obligation to preserve this inventory and of the burdens imposed by this preservation.

For the reasons set forth herein, Ameridose respectfully requests that the Court issue an order permitting it to destroy the recalled inventory.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on April 11, 2014 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

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